



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 8, 2015

CareFusion 2200 Inc.
Ms. Jane Weber
Regulatory Affairs Manager
75 N. Fairway Drive
Vernon Hills, IL 60061

Re: K142529

Trade/Device Name: Genesis™ Reusable Rigid Sterilization Container System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap, Containers, Trays, Cassettes and Other Accessories
Regulatory Class: II
Product Code: KCT
Dated: December 5, 2014
Received: December 8, 2014

Dear Ms. Weber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K142529

Device Name
Genesis Reusable Rigid Sterilization Container System

Indications for Use (Describe)

The Genesis Reusable Rigid Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical device and maintains sterility of the enclosed device until used for a maximum of 180 days.

Containers are suitable for dynamic air removal (pre-vacuum) steam sterilization, immediate use pre-vacuum steam sterilization and 100% ethylene oxide sterilization when used as described in the instructions for use.

Reusable baskets and accessory items (pins, dividers, mats, etc.) are intended to organize and secure enclosed medical devices during sterilization and storage of the container.

Data cards are used to record information regarding a specific sterilization process load. Filter media allows ingress and egress of sterilant while providing a microbial barrier. Tamper evident arrows provide a visual indication that the container system has not been inadvertently opened prior to use. Each arrow contains a modality-specific external process indicator that serves as a visual indication that the system has been exposed to a specific sterilization cycle parameter. Data cards, filters and tamper evident arrows are single use only.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Sterilization Parameters for the Genesis™ Reusable Rigid Container System by Modality

Sterilization Method	Cycle Parameters	Total System Weight	Applicable Containers/Accessories
Dynamic Air Removal (Pre-Vacuum) Steam	<p>Exposure Temperature: 270°F (132°C)</p> <p>Pre-Conditioning Pulses: 3</p> <p>Exposure Time: 4 Minutes</p> <p>Dry Time Cycle: 30 minutes</p> <p>Minimum Cool Time: 60 minutes (may vary according to load contents)</p> <p>Stack Height: Maximum 3</p>	25 lbs.	<p>Solid Bottom Containers; Perforated Bottom Containers; Stacking Baskets Non-Stacking Baskets Lumen Devices (2.68 mm x 450 mm) – Qty 16 Lumen Devices (1.37 mm x 242 mm) – Qty 10 Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats Laparoscopic Racks Optional Protective Plate Materials: Metals, Polymers, Composites</p>
Dynamic Air Removal (Pre-Vacuum) Steam Immediate Use	<p>Exposure Temperature: 270°F (132°C)</p> <p>Pre-Conditioning Pulses: 3</p> <p>Exposure Time: 4 Minutes</p> <p>Stack Height: Maximum 3</p> <p>Note: Devices must be used immediately and cannot be stored for later use.</p>	25 lbs.	<p>Solid Bottom Containers; Perforated Bottom Containers; Stacking Baskets Non-Stacking Baskets Lumen Devices (2.68 mm x 450 mm) – Qty 16 Lumen Devices (1.37 mm x 242 mm) – Qty 10 Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats Laparoscopic Racks Optional Protective Plate</p> <p>*Materials: Metals, Polymers, Composites</p>
100% Ethylene Oxide	<p>EO Sterilant Concentration: 100% EO, 725 mg/L</p> <p>Pre-Conditioning Time: 30 minutes</p> <p>Temperature: 130°F (55°C)</p> <p>Exposure Time: 60 minutes</p> <p>Relative Humidity: 50-80%</p> <p>Aeration: 8 hours @ 109.4°F (43°C)</p> <p>No stacking</p>	15 lbs.	<p>Perforated Bottom Containers except CD2-10BDL and DINCD2-8B); Non Stacking Baskets Lumen Devices (3.0 mm x 400 mm) – Qty 5 Device or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars; Laparoscopic Racks;</p> <p>Materials: Stainless Steel, Aluminum, Silicone, Radel</p>

Examples of instrument types that are conjoined include: scissors, forceps, clamps (including double action), hand held and self retaining retractors, needle holders, osteotomes/chisels, rongeurs, kerrison rongeurs, specula.

Note: Air tight occluded challenges are devices entailing surfaces that are completely obstructed. These types of devices have not been validated for use in the Genesis Reusable Sterilization Container System.

*Materials: Intrinsically stable metals. Composites, thermoplastics, and thermosetting polymers with constant use temperatures above 135°C.

Examples of intrinsically stable metals include stainless steel, titanium (CP and alloys) and aluminum. Examples of thermoplastic polymers are PEEK, PEKK, PEI (Uitem), Acetal (Delrin), Radel (PPSU), Nylon, PTFE, Polypropylene, ABS (Acrylonitrile/Butadiene/ Styrene) and POM (Polyoxymethylene). Examples of thermosetting polymers are Phenolic and Silicone. Examples of composites include carbon fiber reinforced epoxy (CFRE).

Accessories and Device Challenges by Sterilization Modality and Container Style

Type of Container	Contents/Configuration	Pre-Vacuum Steam	100 % Ethylene Oxide
Solid Bottom Container	Non Stacking Baskets	Yes	No
	Stacking Baskets	Yes	No
	Lumen: 1.37 mm (ID) x 242 mm(L)	Yes, maximum 10	No
	Lumen: 2.68mm (ID) x 450mm (L)	Yes, maximum 16	No
	Lumen: 3 mm (ID) x 400 mm (L)	Yes, maximum 2	No
	Occluded/Mated Challenge	Yes	No
	Silicone Support Bar	Yes	No
	Silicone Mat	Yes	No
	Laparoscopic Rack	Yes	No
	Optional Protective Plate	Yes	No
	Filter	NST Series	No
	Data Card	MD1-1	No
	Tamper-Evident Arrow	White AS Series	No
	Stack Height	3	No
	Materials	Materials: Metals, Polymers, Composites	No
	Maximum Total Container System Weight	25 lbs.	No
Perforated Bottom Container	Non Stacking Baskets	Yes	Yes
	Stacking Baskets	Yes	No
	Lumen: 1.37 mm (ID) x 242 mm(L)	Yes, maximum 10	No
	Lumen: 2.68mm (ID) x 450mm (L)	Yes, maximum 16	No
	Lumen: 3 mm (ID) x 400 mm (L)	Yes, maximum 2	Yes, maximum 5
	Occluded/Mated challenge	Yes	Yes
	Silicone Support Bars	Yes	Yes
	Silicone Mat	Yes	No
	Laparoscopic Rack	Yes	Yes
	Optional Protective Plate	Yes	No
	Filter	NST series	NST series
	Data Cards	MD1-1	MD1-1
	Tamper Evident Arrow	White AS Series	Yellow AG Series
	Stack Height	3 max	No stacking
	Materials	Materials: Metals, Polymers, Composites	Radel, Stainless Steel, Aluminum, Silicone
	Maximum Total Weight	25 lbs.	15 lbs.
STERRAD Compatible Containers	Non Stacking Baskets	Yes	Yes
	Stacking Baskets	Yes	No
	Lumen: 2.68mm (ID) x 450mm (L)	Yes, maximum 2	No
	Lumen: 3.0mm (ID) x 400mm (L)	Yes, maximum 2	Yes, maximum 5
	Occluded/Mated Challenge	Yes	Yes
	Silicone Support Bars	Yes	Yes
	Silicone Mat	Yes	No
	Laparoscopic Rack	Yes	Yes
	Optional Protective Plate	Yes	No
	Filter	NST Series	NST Series
	Data Cards	MD1-1	MD1-1
	Tamper-Evident Arrow	White AS Series	Yellow AG Series
	Stack Height	3 Maximum	No stacking
	Materials	Materials: Metals, Polymers, Composites	Radel, Stainless Steel, Aluminum, Silicone
	Maximum Total Container System Weight	25 lbs.	15 lbs.

Note: The CD2-10BDL and DINCD2-8B container models are not validated for use in 100% Ethylene Oxide sterilization

Solid Bottom Containers

Catalog Code	Description	Container Dimension (in)	Container Weight (lb.)
CD0-4C	Quarter Length Container	9.5 x 12.4 x 3.8	3.4
CD1-4C	Half Length Container	11.8 x 12.4 x 4.5	4.8
CD1-5C	Half Length Container	11.8 x 12.4 x 5.3	5.0
CD1-6C	Half Length Container	11.8 x 12.4 x 6.1	5.2
CD2-4C	Mid Length Container	19.2 x 12.4 x 4.5	6.4
CD2-5C	Mid Length Container	19.2 x 12.4 x 5.3	6.7
CD2-6C	Mid Length Container	19.2 x 12.4 x 6.1	6.9
CD2-8C	Mid Length Container	19.2 x 12.4 x 7.8	7.3
CD3-4C	Full Length Container	23.1 x 12.4 x 4.5	7.8
CD3-5C	Full Length Container	23.1 x 12.4 x 5.3	7.9
CD3-6C	Full Length Container	23.1 x 12.4 x 6.1	8.2
CD3-7C	Full Length Container	23.1 x 12.4 x 7.0	8.5
CD7-5C	Extra Long Container	25.2 x 12.4 x 5.9	8.5
CD7-6C	Extra Long Container	25.2 x 12.4 x 6.7	8.8
CD7-9C	Extra Long Container	25.2 x 12.4 x 8.4	9.7
CD4-3C	Small Narrow Container	20.8 x 7.3 x 3.9	4.2
CD4-5C	Small Narrow Container	20.8 x 7.3 x 5.2	5.2
CD5-3C	Large Narrow Container	28.1 x 11.2 x 5.0	8.4
CD5-61C	Large Narrow Container	28.1 x 11.2 x 6.4	9.1
CD0-3C	Mini Container	10.2 x 7.2 x 3.2	2.5
CD6-6C	Retractor Container	26.5 x 17.0 x 6.9	12.4
CD1-7CDL	Half Length Container	11.9 x 12.5 x 7.5	5.3
CD1-8CDL	Half Length Container	11.9 x 12.5 x 8.3	5.5
CD2-7CDL	Half Length Container	19.2 x 12.5 x 7.0	7.1
CD2-10CDL	Mid Length Container	19.2 x 12.5 x 9.4	8.2
CD3-8CDL	Full Length Container	23.1 x 12.5 x 7.8	8.8
CD3-9CDL	Full Length Container	23.1 x 12.5 x 8.8	8.6
DINCD3-5C	Full Length DIN Container	23.1 x 11.4 x 5.4	7.9
DINCD3-6C	Full Length DIN Container	23.1 x 11.4 x 6.1	8.2
DINCD3-7C	Full Length DIN Container	23.1 x 11.4 x 7.1	8.5
DINCD2-5C	Mid Length DIN Container	19.2 x 11.4 x 5.4	6.7
DINCD2-6C	Mid Length DIN Container	19.2 x 11.4 x 6.1	6.9
DINCD2-8C	Mid Length DIN Container	19.2 x 11.4 x 7.8	7.3
DINCD1-5C	Half Length DIN Container	11.6 x 11.4 x 5.4	5.0
DINCD1-6C	Half Length Container	11.6 x 11.4 x 6.1	5.2

Perforated Bottom Containers

Catalog Code	Description	Container Dimension (in)	Container Weight (lb.)
CD0-4B	Quarter Length Container	9.5 x 12.4 x 3.8	3.7
CD1-4B	Half Length Container	11.8 x 12.4 x 4.5	5.2
CD1-5B	Half Length Container	11.8 x 12.4 x 5.3	5.5
CD1-6B	Half Length Container	11.8 x 12.4 x 6.1	5.7
CD2-4B	Mid Length Container	19.2 x 12.4 x 4.5	6.8
CD2-5B	Mid Length Container	19.2 x 12.4 x 5.3	7.1
CD2-6B	Mid Length Container	19.2 x 12.4 x 6.1	7.4
CD2-8B	Mid Length Container	19.2 x 12.4 x 7.8	7.8
CD3-4B	Full Length Container	23.1 x 12.4 x 4.5	8.5
CD3-5B	Full Length Container	23.1 x 12.4 x 5.3	8.8
CD3-6B	Full Length Container	23.1 x 12.4 x 6.1	9.0
CD3-7B	Full Length Container	23.1 x 12.4 x 7.0	9.4
CD7-5B	Extra Long Container	25.2 x 12.4 x 5.9	9.0
CD7-6B	Extra Long Container	25.2 x 12.4 x 6.7	9.4

Catalog Code	Description	Container Dimension (in)	Container Weight (lb.)
CD7-9B	Extra Long Container	25.2 x 12.4 x 8.4	10.0
CD4-3B	Small Narrow Container	20.8 x 7.3 x 3.9	4.5
CD4-5B	Small Narrow Container	20.8 x 7.3 x 5.2	5.0
CD5-3B	Large Narrow Container	28.1 x 11.2 x 5.0	9.1
CD5-61B	Large Narrow Container	28.1 x 11.2 x 6.4	9.5
CD0-3B	Mini Container	10.2 x 7.2 x 3.2	2.6
CD6-6B	Retractor Container	26.5 x 17.0 x 6.9	13.9
CD1-7BDL	Half Length Container	11.9 x 12.5 x 7.5	5.8
CD1-8BDL	Half Length Container	11.9 x 12.5 x 8.3	6.0
CD2-10BDL	Mid Length Container	19.2 x 12.5 x 9.4	8.2
CD2-7BDL	Half Length Container	19.2 x 12.5 x 7.0	7.5
CD3-8BDL	Full Length Container	23.1 x 12.5 x 7.8	9.6
CD3-9BDL	Full Length Container	23.1 x 12.5 x 8.8	9.9
DINCD3-5B	Full Length DIN Container	23.1 x 11.4 x 5.4	8.8
DINCD3-6B	Full Length DIN Container	23.1 x 11.4 x 6.1	9.0
DINCD3-7B	Full Length DIN Container	23.1 x 11.4 x 7.1	9.4
DINCD2-5B	Mid Length DIN Container	19.2 x 11.4 x 5.4	7.1
DINCD2-6B	Mid Length DIN Container	19.2 x 11.4 x 6.1	7.4
DINCD2-8B	Mid Length DIN Container	19.2 x 11.4 x 7.8	7.8
DINCD1-5B	Half Length DIN Container	11.6 x 11.4 x 5.4	5.5
DINCD1-6B	Half Length DIN Container	11.6 x 11.4 x 6.1	5.7

STERRAD Style Containers

Catalog Code	Description	Container Dimension (in)	Container Weight (lb.)
CD0-4ST	Quarter Length Container	9.5 x 12.4 x 3.8	3.7
CD1-4ST	Half Length Container	11.8 x 12.4 x 4.5	5.2
CD1-5ST	Half Length Container	11.8 x 12.4 x 5.3	5.4
CD1-6ST	Half Length Container	11.8 x 12.4 x 6.1	5.6
CD2-4ST	Mid Length Container	19.2 x 12.4 x 4.5	6.8
CD2-5ST	Mid Length Container	19.2 x 12.4 x 5.3	7.0
CD2-6ST	Mid Length Container	19.2 x 12.4 x 6.1	7.2
CD2-8ST	Mid Length Container	19.2 x 12.4 x 7.8	7.7
CD3-4ST	Full Length Container	23.1 x 12.4 x 4.5	8.4
CD3-5ST	Full Length Containers	23.1 x 12.4 x 5.3	8.6
CD3-6ST	Full Length Containers	23.1 x 12.4 x 6.1	8.9
CD3-7ST	Full Length Containers	23.1 x 12.4 x 7.0	9.3
CD4-3ST	Small Narrow Shallow Container	20.8 x 7.3 x 3.9	4.2
CD4-5ST	Small Narrow Container	20.8 x 7.3 x 5.2	4.8
CD5-3ST	Large Narrow Shallow Container	28.1 x 11.2 x 5.0	8.9
CD5-61ST	Large Narrow Shallow Container	28.1 x 11.2 x 6.4	9.4
CD0-3ST	Mini Container	10.2 x 7.2 x 3.2	2.6



K142529 510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

SUBMITTER INFORMATION	
Name	CareFusion 2200 Inc
Address	75 N. Fairway Dr. Vernon Hills, IL 60061
Phone number	(847) 362-8094
Fax number	(312) 949-0272
Establishment Registration Number	1423507
Name of contact person	Jane Weber, Regulatory Affairs Manager
Date prepared	05-JAN-2015
DEVICE INFORMATION	
Trade or proprietary name	Genesis™ Reusable Rigid Sterilization Container System
Common or usual name	Sterilization Container
Classification name	Sterilization Wrap, Containers, Trays, Cassettes and Other Accessories
Classification panel	80
Regulation	Class II per 21CFR 880.6850, Product code KCT
Product Code(s)	KCT
Legally marketed device(s) to which equivalence is claimed	Genesis™ Reusable Sterilization Container System K140850
Reason for 510(k) submission	Expand indications for use regarding the quantity and types of lumen devices to be sterilized using the pre-vacuum steam sterilization modality in the Genesis Container System.
Device description	<p>The Genesis Reusable Rigid Container System is an assortment of rigid, reusable, stackable containers that are used to sterilize other medical devices and maintain sterility of these devices until used. The container system is comprised of a lid, bottom, filter, tamper evident arrows, and data cards.</p> <p>The container system houses baskets of varying depths and organizing accessory devices that are used to organize and to secure surgical instrumentation and/or other medical devices.</p>



SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristic	Predicate Device - K140850	New/Modified Device
Intended Use	A sterilization container system is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed medical device until used.	Same
Container	Anodized aluminum 5000 and 1100 series; stainless steel 300 series	Same
Gasket	Closed cell silicone foam	Same
Filter	SMS polypropylene for all sterilization modalities	Same
Baskets	304 Stainless Steel, electropolished	Same
Dividers, brackets	Aluminum 5000 series	Same
Clips, posts, pins	Stainless steel 300 and 400 series	Same
Silicone bars, mats	Silicone Elastomer	Same
Material Compatibility (materials to be sterilized within container)	Intrinsically stable metals, composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C.	Same
Volume to Vent Ratio	24.0 to 182.3 in ³ / in ²	Same
Sterilization parameters for Pre-Vacuum steam for Lumen devices	Lumens: 2.68 mm (ID) x 450 mm (L) – Qty 2	Lumens: 2.68 mm (ID) x 450 mm (L) – Qty 16 Lumens 1.37 mm (ID) x 242 mm (L) – Qty 10
PERFORMANCE DATA		
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE		
Performance Test Summary-New Device		
Characteristic	Standard/Test/FDA Guidance	Results Summary
Sterilization Efficacy: Pre-vacuum Steam	ST 77 2013 Containment Devices for Reusable Medical Device Sterilization	Testing demonstrated a 12 log reduction and a sterility assurance level (SAL) of 10 ⁻⁶ using biological (BI) overkill method
Dry Time for Dynamic Air Removal (Pre-vacuum steam modality)	ST 77 2013 Containment Devices for Reusable Medical Device Sterilization	Testing demonstrated validated method of drying by absence of visible moisture
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL		



EQUIVALENCE AND/OR OF CLINICAL INFORMATION
N/A – No clinical tests were conducted for this submission.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The Genesis Reusable Rigid Container System has been validated to meet the established performance criteria. The results of the verification studies demonstrate that the sterilization containers perform as intended and based on the nonclinical tests performed the subject device is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate device, Class II (21 CFR 880.6850), Product code KCT.

INDICATIONS FOR USE
<p>The Genesis Reusable Rigid Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It allows sterilization of the enclosed medical device and maintains sterility of the enclosed medical device until used for a maximum of 180 days.</p> <p>Containers are suitable for dynamic air removal (pre-vacuum) steam sterilization, immediate use pre-vacuum steam sterilization and 100% ethylene oxide sterilization when used as described in the instructions for use.</p> <p>Reusable baskets and accessory items (pins, dividers, mats, etc.) are intended to organize and secure enclosed medical devices during sterilization and storage of the container.</p> <p>Data cards are used to record information regarding a specific sterilization process load. Filter media allows ingress and egress of sterilant while providing a microbial barrier. Tamper evident arrows provide a visual indication that the container system has not been inadvertently opened prior to use. Each arrow contains a modality-specific external process indicator that serves as a visual indication that the system has been exposed to a specific sterilization cycle parameter. Data cards, filters and tamper evident arrows are single use only.</p>



Sterilization Parameters for the Genesis Reusable Rigid Container System by Modality

Sterilization Method	Cycle Parameters	Total System Weight	Applicable Containers/Accessories
Dynamic Air Removal (Pre-Vacuum) Steam	Exposure Temperature: 270°F (132°C) Pre-Conditioning Pulses: 3 Exposure Time: 4 Minutes Dry Time Cycle: 30 minutes Minimum Cool Time: 60 minutes (may vary according to load contents) Stack Height: Maximum 3	25 lbs.	Solid Bottom Containers; Perforated Bottom Containers; Stacking Baskets Non-Stacking Baskets Lumen Devices (2.68 mm x 450 mm) – Qty 16 Lumen Devices (1.37 mm x 242 mm) – Qty 10 Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats Laparoscopic Racks Optional Protective Plate Materials: Metals, Polymers, Composites
Dynamic Air Removal (Pre-Vacuum) Steam Immediate Use	Exposure Temperature: 270°F (132°C) Pre-Conditioning Pulses: 3 Exposure Time: 4 Minutes Stack Height: Maximum 3 Note: Devices must be used immediately and cannot be stored for later use.	25 lbs.	Solid Bottom Containers; Perforated Bottom Containers; Stacking Baskets Non-Stacking Baskets Lumen Devices (2.68 mm x 450 mm) – Qty 16 Lumen Devices (1.37 mm x 242 mm) – Qty 10 Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats Laparoscopic Racks Optional Protective Plate *Materials: Metals, Polymers, Composites
100% Ethylene Oxide	EO Sterilant Concentration: 100% EO, 725 mg/L Pre-Conditioning Time: 30 minutes Temperature: 130°F (55°C) Exposure Time: 60 minutes Relative Humidity: 50-80% Aeration: 8 hours @ 109.4°F (43°C) No stacking	15 lbs.	Perforated Bottom Containers except CD2-10BDL and DINCD2-8B); Non Stacking Baskets Lumen Devices (3.0 mm x 400 mm) – Qty 5 Device or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars; Laparoscopic Racks; Materials: Stainless Steel, Aluminum, Silicone, Radel



Examples of instrument types that are conjoined include: scissors, forceps, clamps (including double action), hand held and self retaining retractors, needle holders, osteotomes/chisels, rongeurs, kerrison rongeurs, specula.

Note: Air tight occluded challenges are devices entailing surfaces that are completely obstructed. These types of devices have not been validated for use in the Genesis Reusable Sterilization Container System.

*Materials: Intrinsically stable metals. Composites, thermoplastics, and thermosetting polymers with constant use temperatures above 135°C.

Examples of intrinsically stable metals include stainless steel, titanium (CP and alloys) and aluminum. Examples of thermoplastic polymers are PEEK, PEKK, PEI (Ultem), Acetal (Delrin), Radel (PPSU), Nylon, PTFE, Polypropylene, ABS (Acrylonitrile/Butadiene/ Styrene) and POM (Polyoxymethylene). Examples of thermosetting polymers are Phenolic and Silicone. Examples of composites include carbon fiber reinforced epoxy (CFRE).



Accessories and Device Challenges by Sterilization Modality and Container Style

Type of Container	Contents/Configuration	Pre-Vacuum Steam	100 % Ethylene Oxide
Solid Bottom Container	Non Stacking Baskets	Yes	No
	Stacking Baskets	Yes	No
	Lumen: 1.37 mm (ID) x 242 mm(L)	Yes, maximum 10	No
	Lumen: 2.68mm (ID) x 450mm (L)	Yes, maximum 16	No
	Lumen: 3 mm (ID) x 400 mm (L)	Yes, maximum 2	No
	Occluded/Mated Challenge	Yes	No
	Silicone Support Bar	Yes	No
	Silicone Mat	Yes	No
	Laparoscopic Rack	Yes	No
	Optional Protective Plate	Yes	No
	Filter	NST Series	No
	Data Card	MD1-1	No
	Tamper-Evident Arrow	White AS Series	No
	Stack Height	3	No
	Materials	Materials: Metals, Polymers, Composites	No
	Maximum Total Container System Weight	25 lbs.	No
Perforated Bottom Container	Non Stacking Baskets	Yes	Yes
	Stacking Baskets	Yes	No
	Lumen: 1.37 mm (ID) x 242 mm(L)	Yes, maximum 10	No
	Lumen: 2.68mm (ID) x 450mm (L)	Yes, maximum 16	No
	Lumen: 3 mm (ID) x 400 mm (L)	Yes, maximum 2	Yes, maximum 5
	Occluded/Mated challenge	Yes	Yes
	Silicone Support Bars	Yes	Yes
	Silicone Mat	Yes	No
	Laparoscopic Rack	Yes	Yes
	Optional Protective Plate	Yes	No
	Filter	NST series	NST series
	Data Cards	MD1-1	MD1-1
	Tamper Evident Arrow	White AS Series	Yellow AG Series
	Stack Height	3 max	No stacking
	Materials	Materials: Metals, Polymers, Composites	Radel, Stainless Steel, Aluminum, Silicone
	Maximum Total Weight	25 lbs.	15 lbs.
STERRAD Compatible Containers	Non Stacking Baskets	Yes	Yes
	Stacking Baskets	Yes	No
	Lumen: 2.68mm (ID) x 450mm (L)	Yes, maximum 2	No
	Lumen: 3.0mm (ID) x 400mm (L)	Yes, maximum 2	Yes, maximum 5
	Occluded/Mated Challenge	Yes	Yes
	Silicone Support Bars	Yes	Yes
	Silicone Mat	Yes	No
	Laparoscopic Rack	Yes	Yes
	Optional Protective Plate	Yes	No
	Filter	NST Series	NST Series
	Data Cards	MD1-1	MD1-1
	Tamper-Evident Arrow	White AS Series	Yellow AG Series
	Stack Height	3 Maximum	No stacking
	Materials	Materials: Metals, Polymers, Composites	Radel, Stainless Steel, Aluminum, Silicone
	Maximum Total Container System Weight	25 lbs.	15 lbs.

Note: The CD2-10BDL and DINCD2-8B container models are not validated for use in 100% Ethylene Oxide sterilization

**Solid Bottom Containers**

Catalog Code	Description	Container Dimension (in)	Container Weight (lb.)
CD0-4C	Quarter Length Container	9.5 x 12.4 x 3.8	3.4
CD1-4C	Half Length Container	11.8 x 12.4 x 4.5	4.8
CD1-5C	Half Length Container	11.8 x 12.4 x 5.3	5.0
CD1-6C	Half Length Container	11.8 x 12.4 x 6.1	5.2
CD2-4C	Mid Length Container	19.2 x 12.4 x 4.5	6.4
CD2-5C	Mid Length Container	19.2 x 12.4 x 5.3	6.7
CD2-6C	Mid Length Container	19.2 x 12.4 x 6.1	6.9
CD2-8C	Mid Length Container	19.2 x 12.4 x 7.8	7.3
CD3-4C	Full Length Container	23.1 x 12.4 x 4.5	7.8
CD3-5C	Full Length Container	23.1 x 12.4 x 5.3	7.9
CD3-6C	Full Length Container	23.1 x 12.4 x 6.1	8.2
CD3-7C	Full Length Container	23.1 x 12.4 x 7.0	8.5
CD7-5C	Extra Long Container	25.2 x 12.4 x 5.9	8.5
CD7-6C	Extra Long Container	25.2 x 12.4 x 6.7	8.8
CD7-9C	Extra Long Container	25.2 x 12.4 x 8.4	9.7
CD4-3C	Small Narrow Container	20.8 x 7.3 x 3.9	4.2
CD4-5C	Small Narrow Container	20.8 x 7.3 x 5.2	5.2
CD5-3C	Large Narrow Container	28.1 x 11.2 x 5.0	8.4
CD5-61C	Large Narrow Container	28.1 x 11.2 x 6.4	9.1
CD0-3C	Mini Container	10.2 x 7.2 x 3.2	2.5
CD6-6C	Retractor Container	26.5 x 17.0 x 6.9	12.4
CD1-7CDL	Half Length Container	11.9 x 12.5 x 7.5	5.3
CD1-8CDL	Half Length Container	11.9 x 12.5 x 8.3	5.5
CD2-7CDL	Half Length Container	19.2 x 12.5 x 7.0	7.1
CD2-10CDL	Mid Length Container	19.2 x 12.5 x 9.4	8.2
CD3-8CDL	Full Length Container	23.1 x 12.5 x 7.8	8.8
CD3-9CDL	Full Length Container	23.1 x 12.5 x 8.8	8.6
DINCD3-5C	Full Length DIN Container	23.1 x 11.4 x 5.4	7.9
DINCD3-6C	Full Length DIN Container	23.1 x 11.4 x 6.1	8.2
DINCD3-7C	Full Length DIN Container	23.1 x 11.4 x 7.1	8.5
DINCD2-5C	Mid Length DIN Container	19.2 x 11.4 x 5.4	6.7
DINCD2-6C	Mid Length DIN Container	19.2 x 11.4 x 6.1	6.9
DINCD2-8C	Mid Length DIN Container	19.2 x 11.4 x 7.8	7.3
DINCD1-5C	Half Length DIN Container	11.6 x 11.4 x 5.4	5.0
DINCD1-6C	Half Length Container	11.6 x 11.4 x 6.1	5.2

Perforated Bottom Containers

Catalog Code	Description	Container Dimension (in)	Container Weight (lb.)
CD0-4B	Quarter Length Container	9.5 x 12.4 x 3.8	3.7
CD1-4B	Half Length Container	11.8 x 12.4 x 4.5	5.2
CD1-5B	Half Length Container	11.8 x 12.4 x 5.3	5.5
CD1-6B	Half Length Container	11.8 x 12.4 x 6.1	5.7
CD2-4B	Mid Length Container	19.2 x 12.4 x 4.5	6.8
CD2-5B	Mid Length Container	19.2 x 12.4 x 5.3	7.1
CD2-6B	Mid Length Container	19.2 x 12.4 x 6.1	7.4
CD2-8B	Mid Length Container	19.2 x 12.4 x 7.8	7.8
CD3-4B	Full Length Container	23.1 x 12.4 x 4.5	8.5
CD3-5B	Full Length Container	23.1 x 12.4 x 5.3	8.8
CD3-6B	Full Length Container	23.1 x 12.4 x 6.1	9.0
CD3-7B	Full Length Container	23.1 x 12.4 x 7.0	9.4



Catalog Code	Description	Container Dimension (in)	Container Weight (lb.)
CD7-5B	Extra Long Container	25.2 x 12.4 x 5.9	9.0
CD7-6B	Extra Long Container	25.2 x 12.4 x 6.7	9.4
CD7-9B	Extra Long Container	25.2 x 12.4 x 8.4	10.0
CD4-3B	Small Narrow Container	20.8 x 7.3 x 3.9	4.5
CD4-5B	Small Narrow Container	20.8 x 7.3 x 5.2	5.0
CD5-3B	Large Narrow Container	28.1 x 11.2 x 5.0	9.1
CD5-61B	Large Narrow Container	28.1 x 11.2 x 6.4	9.5
CD0-3B	Mini Container	10.2 x 7.2 x 3.2	2.6
CD6-6B	Retractor Container	26.5 x 17.0 x 6.9	13.9
CD1-7BDL	Half Length Container	11.9 x 12.5 x 7.5	5.8
CD1-8BDL	Half Length Container	11.9 x 12.5 x 8.3	6.0
CD2-10BDL	Mid Length Container	19.2 x 12.5 x 9.4	8.2
CD2-7BDL	Half Length Container	19.2 x 12.5 x 7.0	7.5
CD3-8BDL	Full Length Container	23.1 x 12.5 x 7.8	9.6
CD3-9BDL	Full Length Container	23.1 x 12.5 x 8.8	9.9
DINCD3-5B	Full Length DIN Container	23.1 x 11.4 x 5.4	8.8
DINCD3-6B	Full Length DIN Container	23.1 x 11.4 x 6.1	9.0
DINCD3-7B	Full Length DIN Container	23.1 x 11.4 x 7.1	9.4
DINCD2-5B	Mid Length DIN Container	19.2 x 11.4 x 5.4	7.1
DINCD2-6B	Mid Length DIN Container	19.2 x 11.4 x 6.1	7.4
DINCD2-8B	Mid Length DIN Container	19.2 x 11.4 x 7.8	7.8
DINCD1-5B	Half Length DIN Container	11.6 x 11.4 x 5.4	5.5
DINCD1-6B	Half Length DIN Container	11.6 x 11.4 x 6.1	5.7

STERRAD Style Containers

Catalog Code	Description	Container Dimension (in)	Container Weight (lb.)
CD0-4ST	Quarter Length Container	9.5 x 12.4 x 3.8	3.7
CD1-4ST	Half Length Container	11.8 x 12.4 x 4.5	5.2
CD1-5ST	Half Length Container	11.8 x 12.4 x 5.3	5.4
CD1-6ST	Half Length Container	11.8 x 12.4 x 6.1	5.6
CD2-4ST	Mid Length Container	19.2 x 12.4 x 4.5	6.8
CD2-5ST	Mid Length Container	19.2 x 12.4 x 5.3	7.0
CD2-6ST	Mid Length Container	19.2 x 12.4 x 6.1	7.2
CD2-8ST	Mid Length Container	19.2 x 12.4 x 7.8	7.7
CD3-4ST	Full Length Container	23.1 x 12.4 x 4.5	8.4
CD3-5ST	Full Length Containers	23.1 x 12.4 x 5.3	8.6
CD3-6ST	Full Length Containers	23.1 x 12.4 x 6.1	8.9
CD3-7ST	Full Length Containers	23.1 x 12.4 x 7.0	9.3
CD4-3ST	Small Narrow Shallow Container	20.8 x 7.3 x 3.9	4.2
CD4-5ST	Small Narrow Container	20.8 x 7.3 x 5.2	4.8
CD5-3ST	Large Narrow Shallow Container	28.1 x 11.2 x 5.0	8.9
CD5-61ST	Large Narrow Shallow Container	28.1 x 11.2 x 6.4	9.4
CD0-3ST	Mini Container	10.2 x 7.2 x 3.2	2.6